

Functional optical zone and visual quality after SMILE and FS-LASIK treatment for high myopia

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Research article

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Abstract

Background We compared the functional optical zone (FOZ) and wavefront aberrations achieved after small-incision lenticule extraction (SMILE) and femtosecond laser-assisted in situ keratomileusis (FS-LASIK) in high-myopia patients.

METHODS Thirty four and forty high myopic (spherical equivalent refraction $\leq -6D$) patients were respectively enrolled in FS-LASIK group and SMILE group, only right eye of each patient was analyzed. The planned FOZ (PFOZ), ablation depth/lenticule thickness and other data were acquired from medical records. The achieved FOZs (AFOZ) were assessed using a Pentacam at 1 month, 3 month, 6 month post-surgery. We defined the AFOZ diameter as the mean ring diameter corresponding to average total corneal refractive power (TCRP) in the central 4-mm zone plus 0.5D. The wavefront aberrations were obtained with WASCA system pre-operatively and 6-month-postoperatively.

RESULTS The PFOZs in the SMILE and FS-LASIK groups were 6.57 ± 0.22 mm vs 6.54 ± 0.15 mm ($P = 0.350$). In both groups, the AFOZ at every follow-up point was smaller than the PFOZ ($P < 0.001$). The AFOZ correlated negatively with the wavefront higher order aberrations (HOA), spherical aberration in both groups. HOA, spherical aberration ($P < 0.001$), but not coma ($P = 0.477$) and trefoil ($P = 0.812$), differed significantly between the groups.

CONCLUSIONS In high-myopia patients, the AFOZ was smaller than the PFOZ, irrespective of whether SMILE or FS-LASIK. In SMILE group, the AFOZ was larger and more consistent with the PFOZ, probably resulting in with less wavefront aberrations.

Background

Corneal refractive surgery corrects ametropia by removing the corneal stroma and accordingly changing the anterior corneal refractive power. However, due to the limited corneal thickness, the treatment region, named the functional optical zone (FOZ), cannot cover the whole cornea. The FOZ is defined as the area with the best visual quality and least aberration typically associated with the anterior corneal power distribution. Some studies have defined the FOZ as the area represented by power within the $\pm 0.5 D$ range over the central 4 mm.(1) It is also regarded as the area with the best optical quality, providing visual acuity of no less than 20/32.(2)

Small incision lenticule extraction (SMILE) and femtosecond laser-assisted in situ keratomileusis (FS-LASIK) are widely used lamellar corneal refractive surgeries. SMILE creates a lenticule with a specific shape, according to the attempted correction, after two femtosecond scans at different depths.(3) LASIK aims to reconstruct the corneal anterior surface by ablating the corneal stroma.(4) While several studies have been conducted regarding FOZ after LASIK,(5) few such studies have been published on SMILE. As these procedures use different mechanisms, we considered whether there were differences in the achieved FOZ (AFOZ) between SMILE and LASIK and whether the AFOZ diameters correlated with visual quality results after these two surgeries.

The current study compared the AFOZ between SMILE and FS-LASIK, also investigated the corneal power distribution and wavefront aberrations after surgery.

Methods

The present retrospective study enrolled 74 myopic eyes (all right eyes) from 74 consecutive patients (SMILE: n = 40, FS-LASIK: n = 34) at the Refractive Center of The Eye and ENT Hospital of Fudan University, from December 2017 to March 2018. The current study was performed in accordance with the tenets of the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of the Fudan University EENT Hospital Review Board.

All patients underwent routine ophthalmic evaluation procedures preoperatively, including slit-lamp examination, fundus examination, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), objective (ARK-510A, NIDEK, Tokyo, Japan) and manifest refraction (RT-5100, NIDEK) in microcoria and in a cycloplegic state, corneal topography (Pentacam HR, Oculus, Wetzlar, Germany), intraocular pressure measurement (TX-20, Canon, Tokyo, Japan), axial length measurement (IOLMaster, Carl Zeiss Meditec AG, Jena, Germany), and wavefront aberrations (WASCA, Meditec Carl Zeiss, Germany).

Patients with an excessively thin cornea ($< 480 \mu\text{m}$); those diagnosed with or suspected of keratoconus; and those with other ocular diseases or systemic diseases were excluded. Patients were required to stop wearing soft contact lens at least 1 week before surgery, rigid contact lens at least 2 weeks before surgery, and remain without orthokeratology at least 4 weeks before surgery. Antibiotics eyedrop were delivered 4 times daily for 3 days before surgery.

Small-incision lenticule extraction procedure

All the SMILE procedures were performed via VisuMax (Carl Zeiss Meditec AG), with the energy set at 130 nJ and a repetition rate of 500 kHz, with a spot spacing of $4.5 \mu\text{m}$. The cap diameter was designed to be 7.5 mm, with thickness ranging from 110 to $120 \mu\text{m}$. The lenticule diameter was 5.8–6.7 mm. The side-cut angle was 90° at the superior position. The transition zone was 0.1 mm for astigmatism correction. The target refraction was set to 0 to + 0.75 DS on the basis of age and preoperative refractive power.

The patient was required to stare at the green light throughout the operation. The surgeon centered the corneal vertex by observing through the microscope and moving the joystick. Suction was activated when the watermark exceeded 80% of the cone; then, the eyeball was fixed and photodisruption was created to generate the posterior surface and the anterior surface of the refractive lenticule, followed by a single side-cut incision. The lenticule was then dissected through the side-cut incision and removed manually using microforceps.

FS-LASIK Procedure

Flaps were cut using the VisuMax femtosecond laser, with energy set at 180 nJ and a repetition rate set at 500 kHz. The flap diameter was intended to be 8.5 mm, and the thickness was 110 μm . The side-cut angle was 90°, with a 4-mm-wide hinge immediately above. The corneal stroma was ablated using the MEL 80 excimer laser (Carl Zeiss Meditec AG), with energy set at 0.9 mJ and a repetition rate set at 250 Hz. The targeted diopter was set as 0 to +0.75 DS. The ablation optical zone was centered on the intersection of the optical axis and the corneal plane, and its diameters were set at 5.75 mm to 6.75 mm, with a 2-mm transition zone. A bandage contact lens (ACUVEOASYS, Inc., Jacksonville, FL) was placed after the flap was well repositioned.

Post-operative management and follow-up

After both procedures, 0.5% ofloxacin eye drops (Santen Pharmaceutical Co., Ltd., Osaka, Japan) were instilled 4 times daily for 1 week, 0.1% fluorometholone eye drops (Santen, Pharmaceutical Co., Ltd.) were instilled 4 times daily for 4 weeks, and 0.3% sodium hyaluronate eye drops (Santen, Pharmaceutical Co., Ltd.) were instilled 4 times daily for 2–3 months.

The bandage lenses were removed 1 day after FS-LASIK. Patients were followed up at 1 day, 1 month, 3 month, and 6 month postoperatively. Slit-lamp examination, UDVA, CDVA, and intraocular pressure measurement were performed at each visit. Corneal topography (Pentacam HR, Oculus, Germany) examinations were performed at 1 month, 3 month, and 6 month postoperatively. Wavefront aberrations was examined at 6 month after the surgery.

FOZ and wavefront aberration measurements

Topography was performed by the same experienced technician using the same machine (Pentacam) preoperatively, 1 month, 3 month, and 6 month postoperatively, and only scans marked “OK” by the instrument were saved and analyzed. Calculations were available in the “Power Distribution” scan in the Pentacam. Centered on the corneal apex, the average total corneal refractive power (TCRP) in the central 4-mm zone was regarded as the baseline. By adjusting the diameter of the ring, the AFOZ was acquired as the largest diameter when the mean ring TCRP did not exceed 0.5 D more than the baseline value (*Figure 1*). A threshold value of 0.5D was arbitrarily chosen, because a -0.5 D defocus generally induces a UDVA of 20/32, which allows for daily-life activities to be performed.⁽⁶⁾ Wavefront aberrations with a 5-mm analysis diameter were performed preoperatively and 6-month-postoperatively. The present study analyzed three commonly examined aberrations: spherical aberration, coma, and trefoil, as well as the total high-order aberration (HOA) in OSA-VSIA Zernike polynomials.

For subjective alignment in SMILE and eye movement in FS- LASIK, decentration is inevitable. As one of the factors influencing the FOZ, we measured decentration using Lazaridis’s method.⁽⁷⁾ Using the

thickness difference map in the Pentacam (postoperative 1 month - preoperative), the distance ($r = \sqrt{(x^2 + y^2)}$) from the point with the largest value (x, y) to the corneal vertex (0, 0) was regarded as the decentration value. Because the maximum value point isn't the only one, three consecutive measurements were taken by the same observer and the average values were calculated.

Statistical Analysis

Using SPSS (24.0 IBM Corporation, Armonk, NY), the Kolmogorov-Smirnov test was firstly applied to establish whether the data followed a normal distribution or not. For values with a normal distribution, Student's *t*-test and the paired *t*-test were utilized for between-group and intra-group comparisons, respectively. The FOZs at different timepoints were compared by repeated-measures analysis of variance. Pearson's analysis was then used to assess the relationship between preoperative parameters and AFOZ. For abnormally distributed data, Kruskal-Wallis and Spearman analyses were used. P-values less than 0.05 were considered as indicating statistically significant differences.

Results

Patient characteristics

In total, 74 participants (SMILE group, 40 eyes; FS-LASIK group, 34 eyes) were included in the study. The two groups were comparable in terms of age, spherical equivalent, intraocular pressure (IOP), corneal thickness, ablation depth or lenticule thickness, corneal front mean keratometry (Km), and planned FOZ (PFOZ) (*Table 1*).

Visual outcomes

All surgeries were uneventful, without suction loss, difficult dissection, incomplete scanning, wreck lenticule, and postoperative infection or diffuse lamellar keratitis.

The 6-month postoperative refractive outcomes are shown in *Figure 2*. The safety index (postoperative CDVA/preoperative CDVA) and efficiency index (postoperative UDCA/ preoperative CDVA) were 1.08 ± 0.66 and 1.18 ± 0.43 , respectively, after SMILE and 1.06 ± 0.89 and 1.17 ± 0.88 , respectively, after FS-LASIK ($P > 0.05$).

FOZ

PFOZ was comparable between the two groups, while AFOZs at all three follow-up timepoint were significantly smaller than PFOZ in both groups ($P < 0.001$). AFOZs were significantly larger in the SMILE group than in the FS-LASIK group ($P < 0.001$). However, no significant differences were found among the 3 follow-up points of the FOZ in SMILE group ($P = 0.158$) and FS-LASIK group ($P = 0.216$).

Wavefront aberrations

All four analyzed wavefront aberrations were comparable preoperatively between the two groups (*Figure 3*). Six months after surgery, HOA ($0.44 \pm 0.16 \mu\text{m}$ (S) vs $0.61 \pm 0.22 \mu\text{m}$ (F), $P < 0.001$) and spherical aberration ($0.18 \pm 0.20 \mu\text{m}$ (S) vs $0.30 \pm 0.17 \mu\text{m}$ (F), $P < 0.001$) were significantly different between the two groups, while coma ($0.26 \pm 0.15 \mu\text{m}$ (S) vs $0.23 \pm 0.21 \mu\text{m}$ (F), $P = 0.477$) and trefoil ($0.19 \pm 0.17 \mu\text{m}$ (S) vs $0.18 \pm 0.19 \mu\text{m}$ (F), $P = 0.812$) were comparable between the two groups.

Decentration

Average decentration was comparable in the SMILE and FS-LASIK groups (0.32 ± 0.20 mm in the SMILE group, and 0.29 ± 0.20 mm in the FS-LASIK group, respectively, $P = 0.522$).

Correlation analysis

Spearman analysis revealed that PFOZ correlated with the AFOZ at 6 months postoperatively (SMILE: $r = 0.44$, $P = 0.06$; FS-LASIK: PFOZ: $r = 0.42$, $P = 0.02$). AFOZ was observed to correlate with postoperative HOA ($r = -0.60$, $P < 0.001$), spherical aberration ($r = -0.84$, $P < 0.001$) in the SMILE group. In the FS-LASIK group, AFOZ also correlated with postoperative HOA ($r = -0.39$, $P = 0.046$), spherical aberration ($r = -0.90$, $P < 0.001$) after surgery. Univariate linear regression analysis was performed for AFOZ and PFOZ with equations shown in *Figure 4*.

Discussion

In the present study, we investigated the differences of AFOZ and wavefront aberrations after SMILE and FS-LASIK treatments for high myopia. Our results demonstrated that the AFOZ diameter for SMILE exceeded that of LASIK with equivalent PFOZ design on similar refraction correction. More induction of wavefront aberrations there was after FA-LASIK than SMILE.

To date, there were several methods about the AFOZ by topographic measurement. Though different ways used, it was well accepted that AFOZ would be smaller than programmed treating zone as what the present study showed. Holladay et al. (8) measured the diameter of the optical zone, which involved a steepening of approximately 0.5 D from the central power after LASIK, and found that the optical zone decreased and correlated with the amount of myopic correction. Racine et al. (5) used 0.5 D as a threshold and reported that the corneal topographic effective optical zone decreased postoperatively, but not decreased significantly with the magnitude of refractive correction, possibly due to the absence of high-myopia (≥ -7.00 D) patients with smaller PFOZ (≥ 6.0 mm) constitutes. Both studies found that the outlined area was significantly smaller than the PFOZ. Qian et al. (2) evaluated corneal power distribution after SMILE, and found that the difference between corneal power in the peripheral area and that in the pupil became greater, especially beyond the central 5-mm region. In addition, they found a significant

difference between attempted correction and changed total corneal power. Their study defined the FOZ as the largest ring diameter when the difference between the ring power and the pupil center power was 1.50 D or less, leading to the same conclusion in SMILE correction..

Besides, this study demonstrated SMILE would achieve larger AFOZ than FS-LASIK did on the premise of identical correction design. A possible reason for these findings may be the difference in the mechanism of tissue removal. The excimer laser changes the corneal shape by breaking down molecular bonds and ablating corneal tissues. The region in which the excimer laser releases is distant from the cornea. The excimer laser is perpendicular to the corneal plane when ablating the central cornea, but it is at an angle to the corneal plane when ablating the peripheral cornea. Due to the curvature of the peripheral cornea, part of the energy will be reflected by the cornea, leading to attenuation of the functional laser energy.(9) This effect is similar to the difference in heating effects produced by sunlight on the earth's equator and on the hemispheres. The energy attenuation in the peripheral area reduces the amount of tissue actually ablated and causes a corresponding reduction in the corrected diopter, so that the size of the central cornea with good vision will be reduced. In SMILE, the femtosecond laser scans the corneal stroma twice at different depths, thus isolate a lenticule with specific diopters. Then, the lenticule was extracted through a 2-mm incision, leading to a change in corneal shape.(4) In SMILE, the femtosecond laser is launched closely to the corneal plane, such that there is no peripheral energy attenuation as occurred in FS-LASIK. Moreover, the shape of lenticule is determined by the scan depth, which is not related to the energy value. Therefore, the distribution of corneal refractive power is not significantly different and a larger area of the central cornea with good vision, defined as AFOZ in this study, can be achieved. A continuous observation was performed at three postoperative timepoints, but we found no significant difference in the AFOZs among 1 month, 3month and 6month after both two surgeries. This finding was consistent with what Hou et al(10) reported, who outlined the zero diopter on the tangential curvature difference map as the rim of the effective optical zone measurement.

The present study also compared the wavefront aberrations at 6 month after high myopic correction by SMILE and FS-LASIK. Among the four analyzed wavefront aberrations components, HOA, spherical aberration, and coma were significantly increased in both groups. We also found that more HOA and spherical aberration were induced in FS-LASIK group than that in SMILE group. Our results agree with the results reported by both Ganesh et al(11) and Lin et al(12), which suggested that SMILE might provide better visual quality than FS-LASIK for high myopia. The curvature change of anterior corneal surface is the mechanism for the corneal refractive surgeries. However, these procedures change the anterior corneal surface from a prolate shape to an oblate shape, increase corneal asphericity and, consequently, break the physiological ocular aberration state and cause induction of higher order aberrations. Both Gyldenkerne et al(13) and Zhang et al(14) came to the same conclusion that SMILE preserves the physiological corneal asphericity better than FS-LASIK does, which is related with the tissue removal difference between excimer laser and femtosecond laser. Furthermore, the transition zone and flap design(15, 16), corneal wound healing response and remodeling difference(17) may attribute to more HOA induction in FS-LASIK. The increase in spherical aberration and coma is usually associated with treatment decentration(13, 18). In current study, the decentration in the SMILE and FS-LASIK groups were

comparable, suggesting that decentration has little effect on the conclusions of this study. Another important finding was that the increase of higher order aberrations and spherical aberration were correlated with AFOZ for both SMILE and FS-LASIK procedures, which may provide potential insights into predicting visual quality through AFOZ size.

The limitation of the present study is that it lacked other objective and subjective indicators, such as contrast sensitivity and subjective questionnaire-based visual quality evaluation. Further studies that combine these approaches with visual quality assessment are warranted.

Conclusion

In conclusion, this study compared the corneal power distribution and wavefront aberration after SMILE and LASIK, and identified that AFOZs are larger in SMILE group than FS-LASIK, which would be associated with better optical quality after surgery.

Abbreviation

FOZ:Functional optical zone; SMILE:Small-incision lenticule extraction; FS-LASIK:Femtosecond laser-assisted in situ keratomileusis; PFOZ:Planned functional optical zone;AFOZ:Achieved functional optical zone;HOA:Higher order aberrations; UDVA:Uncorrected distance visual acuity; CDVA:Corrected distance visual acuity; TCRP:Total corneal refractive power; IOP:Intraocular pressure; Km:Corneal front mean keratometry

Declarations

- Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee of Eye, Ear, Nose and Throat Hospital, Fudan university, and was carried out in accordance with the Declaration of Helsinki. Informed written consent was obtained from all participants.

- Consent for publication

Written informed consent was obtained from the patients for publication of this study. Copies of the written consent are available for review by the Editor of this journal.

- Availability of data and material

The datasets during and/or analyzed during the current study available from the corresponding author on reasonable request.

- Competing interests

No competing interests.

•Funding

No financial support was received for this submission.

•Authors' contributions

XD and DF contribute equally for this study. XD conceived of the study and drafted the manuscript. DF collected the data and helped in drafting and revising the manuscript.. MYL critically revised the manuscript.. LW performed the measurements. XTZ performed the surgery and critically revised the manuscript. ZQY conceived of the study and revised the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1 Basic Data of Subjects Included in Study

	SMILE	FS-LASIK	T/c ² value
Patients (male)	40(18)	34(16)	-
Age (years)	28[24-30]	27[25-29]	0.05*
Corneal thickness (µm)	545.74±30.90	545.90±26.75	0.20
Km (D)	43.64±0.92	43.60±1.69	1.03
IOP (mmHg)	16.69 ± 2.76	16.02 ± 2.51	1.09
Corrected spherical equivalent	-7.51±0.81	-7.56±3.45	0.94
Planned functional optical zone(mm)	6.57±0.22	6.54±0.15	0.94
Ablation depth/lenticule thickness (µm)	132.36±14.00	134.89±15.24	-0.74

D = Diopter, Km = mean front corneal keratometry, IOP = Intraocular pressure, * Kruskal-Wallis test, Student's *t* test, all P values > 0.05.

Table 2 Achieved Functional Optical Zone (mm) at 1-month, 3-month, and 6-month postoperative follow-ups in the SMILE Group and FS-LASIK Group

	1 month	3 month	6 month	F-value	P-value
SMILE	5.76±0.37(5.2 to 6.7)	5.79±0.39(5.2 to 6.7)	5.75±0.40(5.0 to 6.8)	2.032	0.158
FS-LASIK	4.41±0.54(3.5 to 5.8)	4.43±0.57(3.4 to 5.7)	4.31±0.66(3.2 to 5.7)	1.572	0.216
T-value	13.20*	14.04*	13.29*		
P-value	0.001	0.001	0.001		

SMILE = small incision lenticule extraction; FS-LASIK= femtosecond laser assisted in situ keratomileusis

Figures

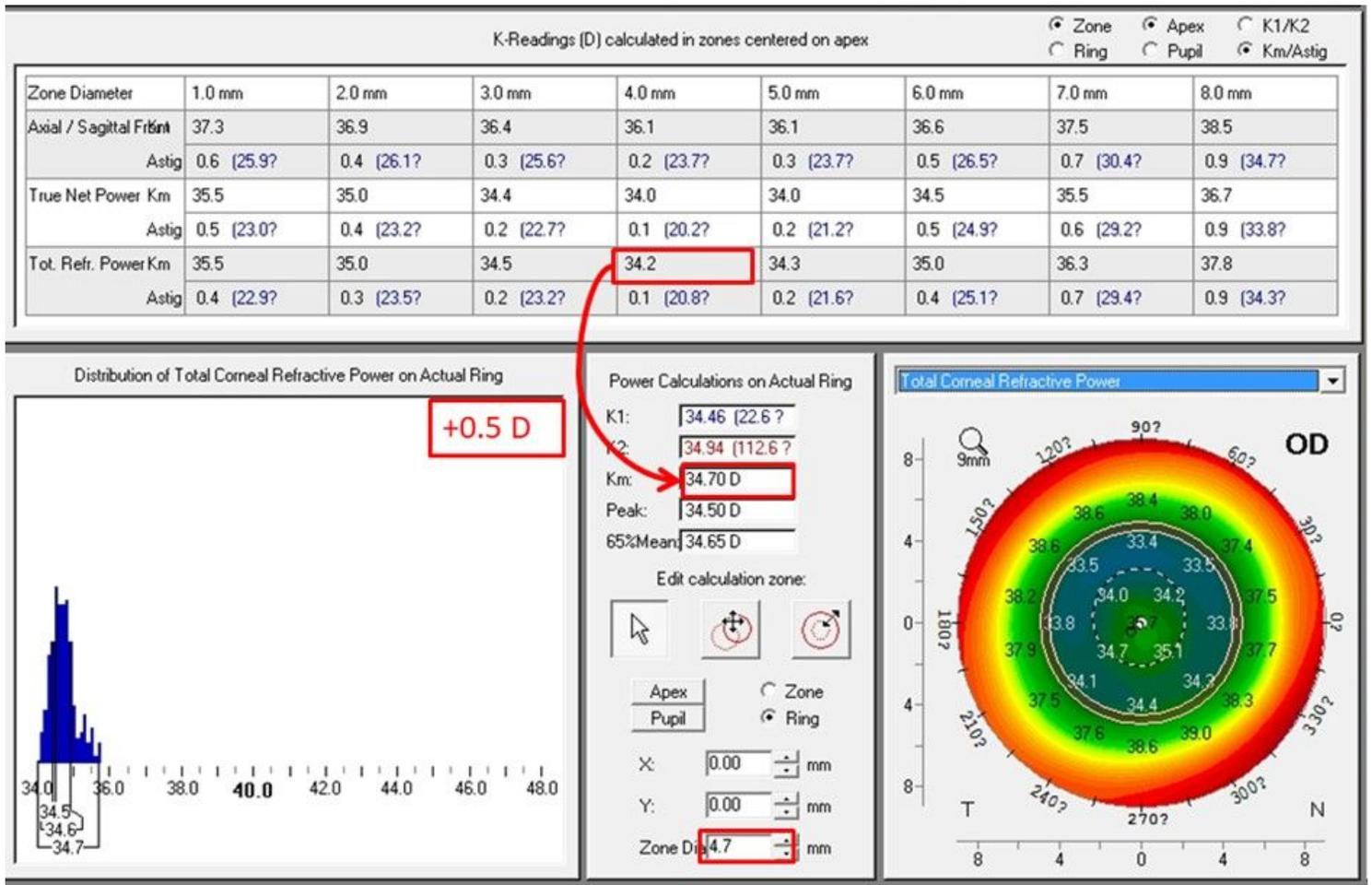
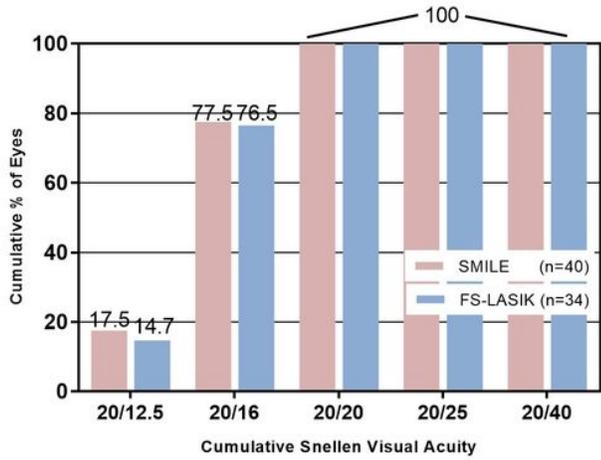
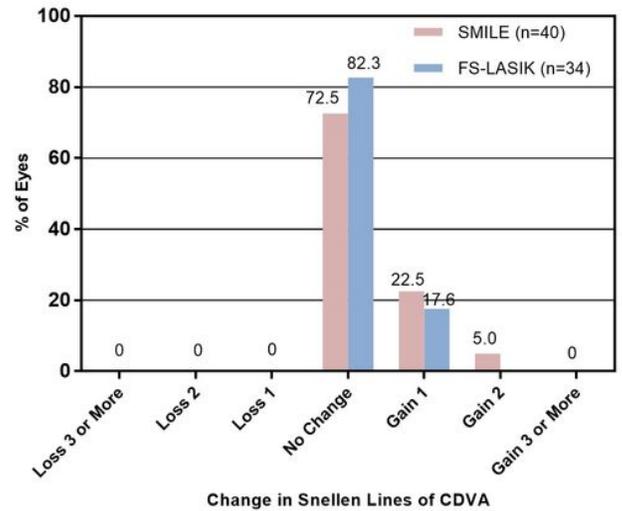


Figure 1

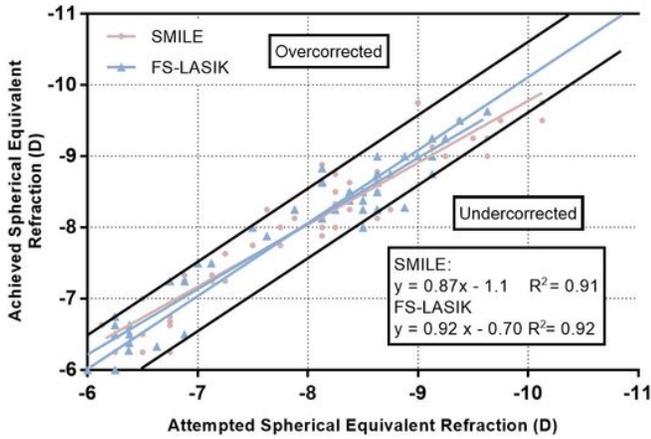
An example of functional optical zone (FOZ) measurement



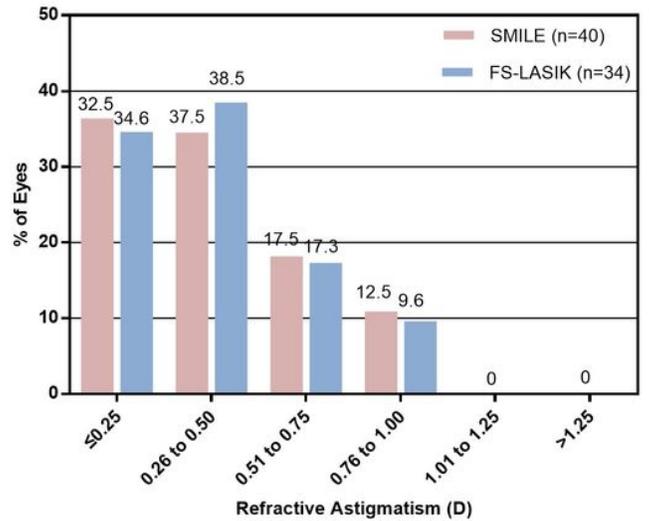
A Uncorrected Distance Visual Acuity



B Change in Corrected Distance Visual Acuity



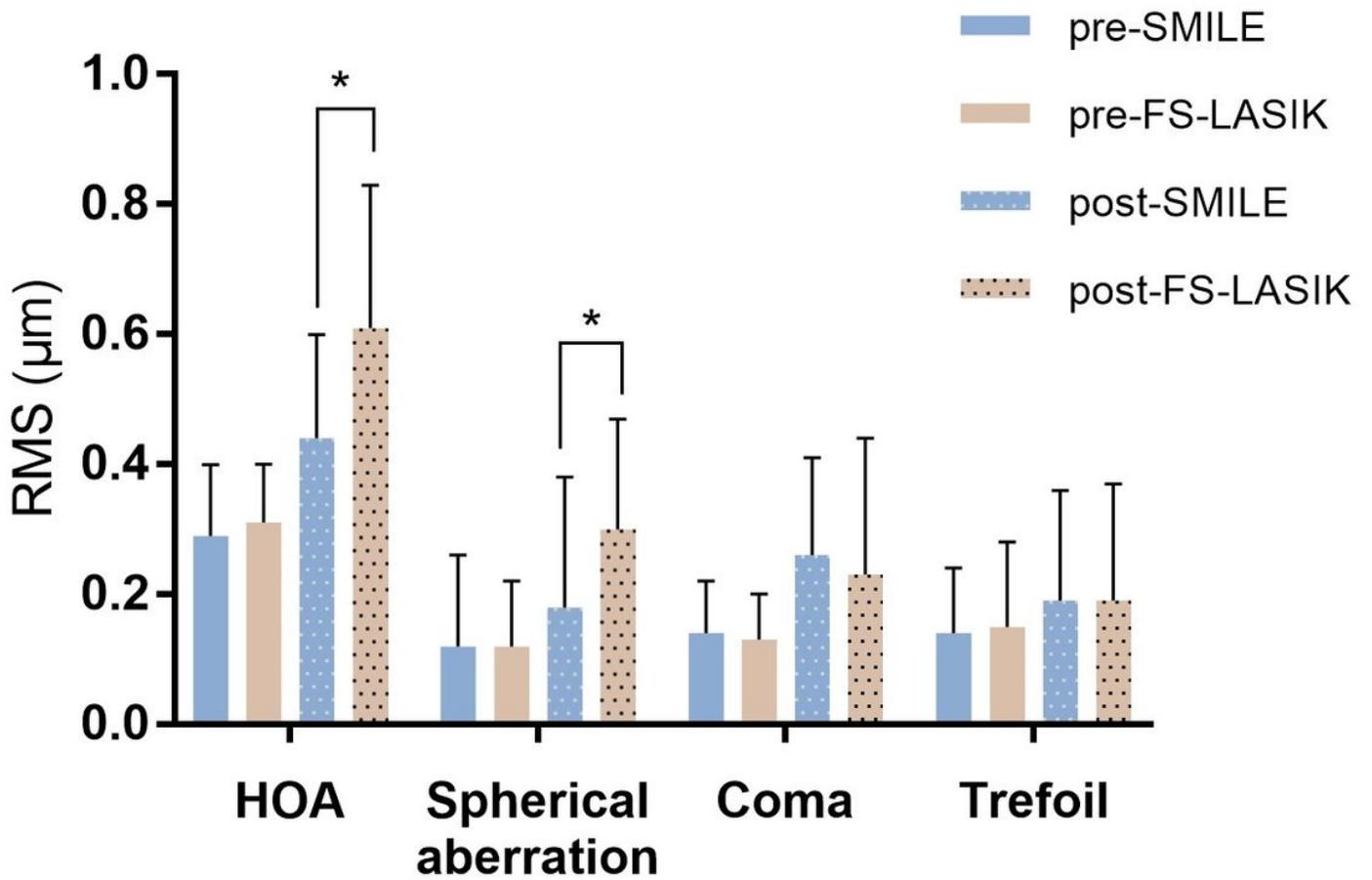
C Spherical Equivalent Attempted vs Achieved



D Refractive Astigmatism

Figure 2

Refractive outcomes. A. Uncorrected distance visual acuity after surgery; B. Changes in corrected distance visual acuity; C. Predictability of attempted correction; D. Refractive astigmatism after surgery



Wavefront aberration before and after surgery

Figure 3

Wavefront aberrations before and 6 month after surgery. RMS = root mean square, HOA = higher order aberration

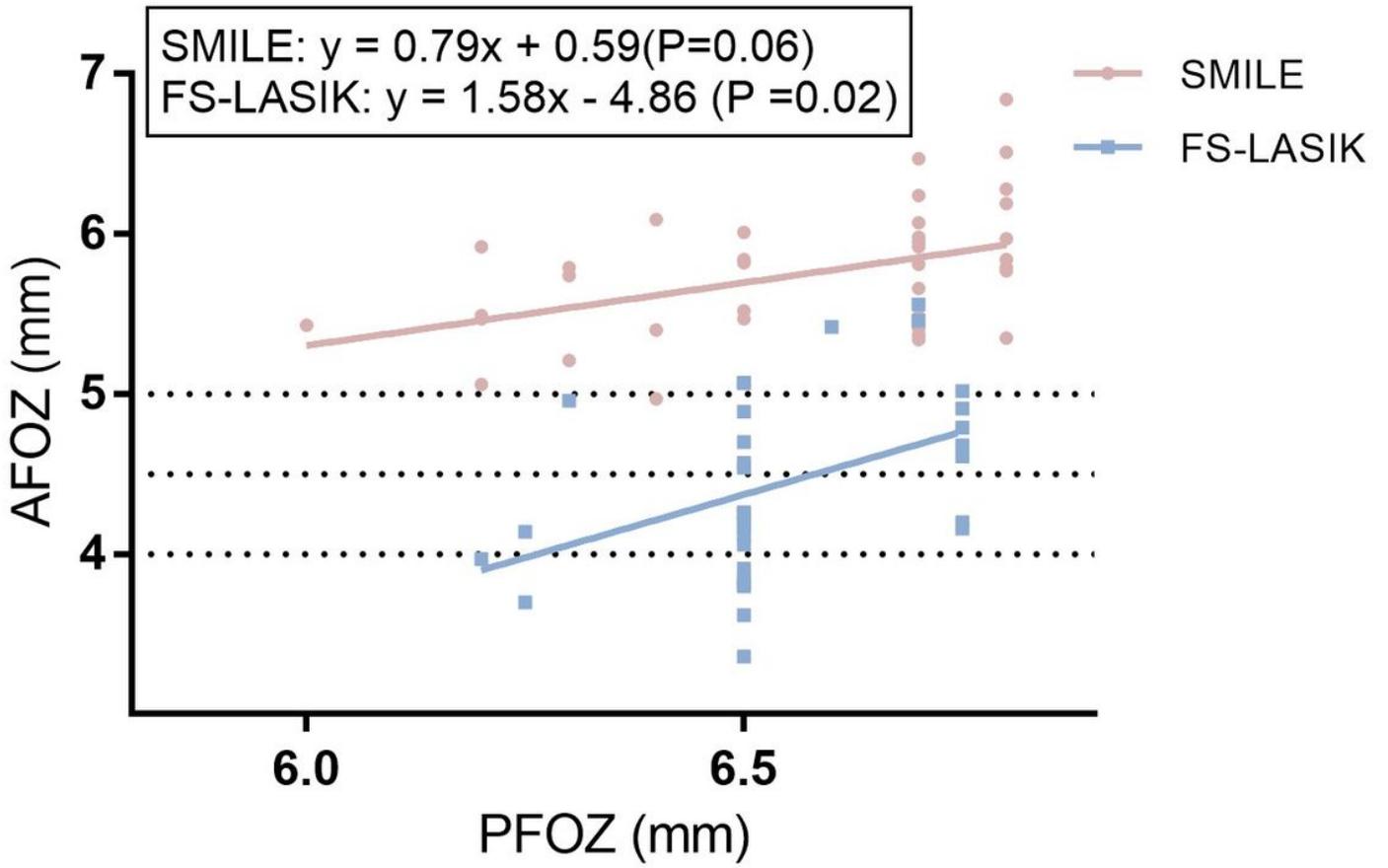


Figure 4

Univariate linear regression of AFOZ and PFOZ. AFOZ = achieved functional optical zone; PFOZ = planned functional optical zone